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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,011	12/11/2003	Teruo Miyazaki	F-8074	2363

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,011	MIYAZAKI, TERUO	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendments filed on December 27, 2004 have been received and entered.

Claims 1-9 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating the immune system of flounders to control infection by *Edwarsiella tarda*, does not reasonably provide enablement for a substance "activating biological functions" in fish and shellfish. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A substance that activates a biological function in a fish or shellfish is broad enough to encompass one that, for example, stimulates growth of the fish or shellfish, or increases fertility or increases swimming speed. Thus, while the specification teaches a substance that activates the immune system of one type of fish, so that that fish produces antibodies that fight one type of bacterial infection, the specification does not teach a substance that activates any biological function in fish or shellfish. One of ordinary skill in the art would have no indication as to what sort of substances would be

effective in activating any other biological function, even stimulation of the immune system in a different type of fish, for example, tuna, to fight infection by a different microbial pathogen. The specification provides no specific guidance for identifying or isolating such substances. Thus, a holding of non-enablement is required.

Additionally, claim 2 recites that the substance activating the biological function may be an inactivated pathogenic virus or bacterium or a pulverized endoparasite. As noted above, the specification, while being enabling for stimulating the immune system of flounders to control infection by *Edwarsiella tarda*, does not reasonably provide enablement for a substance that is an inactivated pathogenic virus or other bacterium or a pulverized endoparasite. The specification provides no specific guidance for the formulation of additives containing these organisms, nor does it provide any evidence that administering such an additive, or a feed containing or coated with such an additive would effectively control infection by one or more of these organisms. Thus, a holding of non-enablement is required.

All of Applicant's arguments have been considered but are not persuasive of error. Applicant assert that the claimed invention is enabled because various substances for activating biological functions in fish and shellfish are well known in the art. The gist of Applicant's invention is the form in which these substances were administered.

In response, Applicant has administered one substance, an inactivated bacterium, to one kind of fish. One of skill in the art would have reasonably expected

that administering an inactivated bacterium, but not any substance with any biological activity, would have activated the immune function of the fish to which the bacterium was administered. One of skill in the art would not have expected that any or all biological functions of the fish that received the bacterium would have been activated. As one of the cited references (Villamar et al., WO 02/00035, discussed below) discloses administering inactivated bacteria in an oil emulsion to produce an immune response in fish generally, one of skill in the art would have expected the inactivated bacterial composition to be effective as an immune system stimulant in more than kind of fish. Accordingly, the rejection of record must be maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Villamar et al. (WO 02/00035). Villamar discloses an additive for fish and shellfish feed that is an emulsion comprising edible oil globules, wherein the oil globules contain a substance that enables a fish or shellfish to fight infection by a microorganism from which the substance is derived. The substance may be inactivated bacterial or yeast cells or fractions thereof. The additive may comprise water and may be formulated to be sprayed on or to coat dry pellets of feed (see p. 8, last paragraph, p. 11, last full

paragraph; p. 12, 2d full paragraph; p. 16 first two full paragraphs; p. 17, first full paragraph; p. 18, first full paragraph and paragraph bridging pp. 18 and 19). With regard to oil microglobules less than 10 μ in diameter, Villamar discloses that the second emulsion, containing an aqueous phase, may be atomized into microcapsules of 20-200 mμ, or 0.02-0.2 μ. These microcapsules contain particles of the oil substance-containing phase that are, therefore, less than 10 μ in diameter (see p. 17, first full paragraph). Accordingly, a holding of anticipation is required.

All of Applicant's arguments have been considered, but are not persuasive of error. Applicant asserts that his invention differs from Villamar in that the claimed invention "consists essentially of" a bioactive substance, a lipophilic emulsifier and an edible oil and optionally contains a hydrophilic emulsifier and water, while the immunogenic compositions of Villamar necessarily contain a cross-linked hydrocolloid polymer.

In response, it is noted that Applicant has amended claim 1 to recite that the additive consists essentially of oil globules, rather than comprises oil globules. But, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude

the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co. , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama - Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988).

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language."). In the instant case, Villamar teaches emulsion 1 (oil droplets

containing a bioactive substance and a lipophilic emulsifier) and emulsion 2 (an aqueous emulsion of emulsion 1). Emulsion 1, which reads on the additive of amended claims 1 and 2, may be used as an additive for fish food without subsequent formulation into emulsion 2. Emulsion 1 may be sprayed or coated onto fish food in pellet or extruded form or any other formed shape that may be top-coated (see pp. 21-22). Emulsion 2 reads on the additive of amended claim 3. Thus, the rejection of record must be maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villamar et al. (WO 02/00035). As discussed above, Villamar discloses an additive for fish and shellfish feed that is an emulsion comprising edible oil globules, wherein the oil globules contain a substance that enables a fish or shellfish to fight infection by a microorganism from which the substance is derived. The substance may be inactivated bacterial or yeast cells or fractions thereof. The additive may comprise water and may be formulated to be sprayed on or to coat dry pellets of feed. Villamar also discloses that the second emulsion, containing an aqueous phase, may be atomized into microcapsules of 20-200 mμ, or 0.02-0.2 μ. These microcapsules contain particles of

the oil substance-containing phase that are, therefore, less than 10 μ in diameter (see p. 8, last paragraph, p. 11, last full paragraph; p. 12, 2d full paragraph; p. 16 first two full paragraphs; p. 17, first full paragraph; p. 18, first full paragraph and paragraph bridging pp. 18 and 19).

The emulsion additive is prepared by mixing the solid biologically active substance, such as probiotic bacteria, with a lipid mixture containing fish oil. This mixture is then mixed vigorously. A second emulsion additive is prepared by combining the first additive with an aqueous polymer suspension and mixing vigorously (see p. 20).

Villamar does not disclose separating the oil globules from the emulsion or stirring and sonicating the emulsion with a homomixer to form microglobules. Villamar also does not disclose mixing an emulsion additive with a feed that is in paste form. Nevertheless, such features as preparing an additive containing oil globules rather than one containing an emulsion containing the oil globules and preparing an emulsion with a homomixer rather than with another emulsifier that performs the same function are result-effective parameters which were well known in the art at the time of Applicant's invention to be routinely optimized by one of ordinary skill in the art of preparing animal feeds. Thus, the claimed variations in Applicant's process with respect to these parameters clearly would have been obvious at the time of Applicant's invention, the optimization of these parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Similarly, the feature of kneading an aqueous-phase-containing emulsion, such as the second emulsion disclosed by Villamar, into a feed in paste form would have been well within the capability of one of

ordinary skill in the art. It would have been apparent to the artisan of ordinary skill that a fish or shellfish feed in paste form and used in water does not have a solid outer surface. Thus, a holding of obviousness is required.

Claims 1-4 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (WO 02/38770). Melvin discloses an oral vaccine for fish to protect fish from bacterial infection in which a biologically active substance, such as inactivated bacteria, may be incorporated into a fish oil with an emulsifier. An emulsion or microparticles containing the biologically active substance may be incorporated into typical fish food and fed to fish. The substance will enter the digestive tract and stimulate an immune response to the substance (p. 11, lines 21-29; p. 13, lines 13-32; p. 14, lines 11-30; p. 15, lines 26-32). The emulsion additive is prepared by mixing the solid biologically active substance, such as inactivated bacteria, with a fish oil containing an emulsifier.

Melvin does not disclose preparing an emulsion containing water or the size of the oil globules. Melvin also does not disclose separating the oil globules from the emulsion or stirring and sonicating the emulsion with a homomixer to form microglobules. Melvin also does not disclose mixing an emulsion additive with a feed that is in paste form.

As discussed above with respect to such features as preparing an additive containing oil globules rather than one containing an emulsion containing the oil globules, preparing an emulsion with a homomixer rather than with another emulsifier,

and combining the additive with feed in paste form rather than in pellet form, features such as the size of the oil globules and the water content of the emulsion are also result-effective parameters which were well known in the art at the time of Applicant's invention to be routinely optimized by one of ordinary skill in the art of preparing animal feeds. Emulsion additives containing water and oil particles containing various biologically active substances may be combined with fish feed to control microbial infection in fish. Thus, the claimed variations in Applicant's process with respect to these parameters clearly would have been obvious at the time of Applicant's invention, the optimization of these parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Thus, a holding of obviousness is required.

All of Applicant's arguments have been considered, but are not persuasive of error. Applicant asserts that his invention differs from Villamar in that the claimed invention, as amended, is a method for producing an additive for fish food "consisting essentially of" a bioactive substance, a lipophilic emulsifier and an edible oil and optionally contains a hydrophilic emulsifier and water, while the immunogenic compositions of Villamar necessarily contain a cross-linked hydrocolloid polymer. Applicant also asserts that Melvin does not teach that the oil globules should be formulated as recited in amended claims 3 and 6, that is, as an aqueous emulsion or suspension, to improve dispersion and maintenance of spherical shape for increased uptake by fish.

As discussed above, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention." When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In the instant case, Applicant has not shown a material difference between an emulsion consisting essentially of oil droplets containing a bioactive substance and a lipophilic emulsifier and an aqueous emulsion containing the oil droplet emulsion, particularly as the oil droplet emulsion may be optionally formulated to contain water and a hydrophilic emulsifier.

Regarding the polymer used in Villamar as a hydrophilic emulsifier to prepare emulsion 2, firstly, an emulsion or suspension in water is a limitation that pertains only to claims 6-9, not to claim 5. Secondly, Villamar discloses that the emulsifier may be a hydrocolloid polymer, such as sodium alginate or potassium carrageenan (see p. 16, 2^{d} and 3^{d} paragraphs). These polymers are not ionically cross-linked. Nevertheless, the reference does not indicate that the polymer in any way affects the biological properties of the emulsion. Because the name or nature of the biologically active substance is not identified in the claims, the composition comprising the biologically active substance does not exclude a compound such as sodium alginate.

Villamar teaches a method of making emulsion 1 (oil droplets containing a bioactive substance and a lipophilic emulsifier) and a method of making emulsion 2 (an

aqueous emulsion of emulsion 1). The method of making and using emulsion 1 renders obvious amended claims 5, 7 and 8, as emulsion 1 may be used as an additive for fish food without subsequent formulation into emulsion 2. Emulsion 1 may be sprayed or coated onto fish food in pellet or extruded form or any other formed shape that may be top-coated (see pp. 21-22). The method of making emulsion 2 renders obvious amended claim 6, which adds the step of preparing an aqueous emulsion or suspension. The method of using emulsion 2 also renders obvious amended claim 9, which recites that the aqueous emulsion or suspension is kneaded into fish food in paste form, because Villamar discloses that emulsion 2 may be mixed with fish food and extruded to form worm-like or noodle shapes (see p. 17, 2^{d} full paragraph).

With regard to the Melvin reference, Applicant asserts that Melvin does not teach an aqueous emulsion or suspension of oil globules, as recited in amended claim 3. Melvin, however, does teach that a preferred mode of administration to fish of the oil emulsion containing a bioactive substance is a type of oral vaccination known as immersion vaccination. In immersion vaccination, the oil emulsion is added directly to the water in which the fish swim, thereby creating a suspension of the oil emulsion in water (see p. 14, lines 20-30).

The rejection of record must therefore be maintained.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-01-14

IRENE MARX
PRIMARY EXAMINER